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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,129	03/08/2004	Gera Strommer	02649/0200987-US0	6958
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER CHIAO, ELMER M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,129

Applicant(s)

STROMMER ET AL.

Examiner

ELMER CHAO

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/14/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Acknowledgement is made of the amendment filed 1/14/2008. However, the claims have not been enter since the finality of that Office Action filed 7/12/2008 is withdrawn.

Claim Objections

2. Claim 16 is objected to because of the following informalities: The phrase "according to said path topological representation" does not make sense. Examiner believes Applicant meant "according to said path from said topological representation" or just "according to said path". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 16, 27-30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilboa (U.S. 2002/0193686).**

Regarding **claims 16 and 32**, Gilboa '686 discloses a method of navigating a probe including the steps of:

establishing a path in said lumen system from a topological representation of the lumen system (Para [0016], establishing a path would be necessary in order to move the catheter); determining a first position of said catheter in said path (Para [0028], "...probe" as used herein should be construed as including...a catheter"; Para [0016], "estimating a location of the target point-of-interest") according to a position signal received of the first position of a distal portion of said catheter (Para [0016], "measuring a location of the probe relative to the reference frame"), and also determining a new position to which said catheter is to be moved based on said determined first position (Para [0016], "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest") and according to said path from said topological representation (Para [0016], "acquiring a plurality of projective images of at least a portion of the body cavity");

operating a moving mechanism (see below) to move said catheter to a second position, according to said new determined position (Para [0016], "moving the probe, within the body cavity");

receiving a position signal as said catheter is moved during said operating step (Para [0016], "measuring a location of the probe relative to the reference frame"), when said second position is substantially identical with said new determined position, determining a further new positions on said path to which

said catheter is to be moved and, when said second position is not identical with said new determined position, determining at least one corrective movement for said catheter (Para [0016], "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest", see below);

and directing said moving mechanism to move said catheter according to said determined corrective movement (Para [0016], "moving the probe, within the body cavity, so as to minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest").

Para [0016] does not explicitly state using a "moving mechanism" to move the catheter. However, it is inherent to use some type of "moving mechanism" in order to move the catheter into and within the body, otherwise it would be impossible to move the catheter. It is well known in the art, that this moving mechanism is traditionally simply the operator's hands, or, at other times, a mechanical moving mechanism can be used as evidenced by Plicchi '566 (Figure 3).

Para [0016] also inherently supports the use of "corrective movements." In order to "minimize a difference between the measured location of the probe and the estimated location of the target point-of-interest" (Para [0016]), it is necessary for the operator to move the catheter towards the point-of-interest with one or more corrective movements.

Gilboa '686 describes the inherency of performing the medical procedure after the navigation of the catheter (Para [0066], "The present invention is of a

method of performing invasive medical procedures ... such as stent deployment in a coronary artery”).

Regarding claim 32, Gilboa '686 inherently discloses moving a catheter in the longitudinal direction. Such a movement is a necessary action when pushing/moving/guiding a catheter to a location of interest.

Regarding **claim 27**, Gilboa '686 further discloses the topological representation being produced by indicating an origin and a destination on an image of at least a portion of said lumen, in a coordinate system respective of said body.

(Para [0074], “...the user changes the coordinates of the point represented by the icon until the icon coincides with the projection of the point-of-interest on each of the images.”; Para [0076], “...only icons representing the locations of the points-of-interest are displayed on a display unit ...along with an icon representative of the true location of the catheter relative to the points of interest”); Para [0077], “if so desired, the points of interest may be displayed superposed on one of the images, from the point of view at which that image was acquired”).

Regarding **claims 28, 29, and 30**, Gilboa '686 further discloses the invention wherein said image is produced by imaging said at least one portion, at least one unparallel imaging planes, one of which is closest to said predetermined path among a plurality of other image planes (Para [0080]).

Para [0080] discloses, “...several images of coronary artery tree 28 are acquired...from several angles; also see figure 3 for “unparallel imaging planes”.

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Regarding claim 29, among the several images, a "closest image" is inherently and necessarily acquired, "closest" being relative to the distances of the other images. Regarding claim 30, Gilboa's technique of acquiring images of the coronary artery tree from several angles implies the images all contain at least a portion of the lumen system of interest, thereby inherently disclosing an "overlap" within the images.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claim 1-9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strommer et al (U.S. 2001/0031919 A1) in view of Ueda (U.S. 5,681,260).**

Regarding **claims 1 and 9**, Strommer '919 discloses a medical imaging and navigation system with a medical positioning system (Figure 1, Item 108) including at least one position detector (Figure 1, Item 162) being attached to the distal portion of catheter (Figure 1, Item 120) (paragraph 0043) (paragraph 0083). Strommer '919 does not disclose a controller with a moving mechanism to move said catheter to said predetermined location. However, Ueda '260

discloses a controller (Figure 5, Item 45) with a moving mechanism (Figure 5, Item 31) in a navigation system used to steer an endoscope or catheter in a human body. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the navigation system as taught by Strommer '919 to be used in conjunction with the moving mechanism and controller as evidenced by Ueda '260. Such a modification would create a catheter navigation system where the controllability is high (C2, L59-62).

Strommer '919 and Ueda '260 do not explicitly teach the system being able to automatically move the catheter. However, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the controller to automatically move the catheter in order to reduce the amount of human interaction necessary. Furthermore, this type of modification can be considered automating a manual activity (see *In re Venner*, 262 F.2d 91, 95, 120, USPQ 237 (CCPA 1955)).

Regarding **claim 9**, the moving mechanism as disclosed by Ueda '260 is fully capable of being disposed of. The examiner wants to make it known to the applicant that most physical matter is capable of disposed of and replaced.

Regarding **claim 2**, Strommer '919 discloses an imaging system (Figure 1, Item 104), a superimposition processor (Figure 1, Item 116) coupled with a display (Figure 1, Item 130)

Regarding **claim 3**, Strommer '919 discloses said display being used to display a superimposed topological representation on the display (paragraph 0047).

Regarding **claim 4**, Strommer '919 discloses said display being used to display a curve respective of the shape of said catheter distal portion (paragraph 0076).

Regarding **claim 5**, Strommer '919 discloses said imaging system being selected from the list consisting of ultra-sound, X-ray, computerized tomography, nuclear magnetic resonance, positron emission tomography, single-photon-emission tomography, and the like (paragraph 0054).

Regarding **claim 6**, Strommer '919 discloses said imaging system further comprising an organ monitor (Figure 1, Item 106) to monitor the organ (paragraph 0046),

Regarding **claim 7**, Strommer '919 discloses a processor (Figure 1, Item 102) coupled with said medical positioning system.

Regarding **claim 8**, Strommer '919 discloses the system wherein said organ monitor is an electrocardiogram (Figure 1, Item 106).

Regarding **claim 12**, Strommer '919 discloses the system wherein said position detector is conductive (Figure 1, the wire connecting Item 106 to 162).

Regarding **claim 13**, Strommer '919 discloses the display in the invention being used to display a real-time visualization of the inspected organ or lumen while superimposing the location of the position sensor(s) mounted on the surgical device. Therefore, the operator is capable of focusing the imaging on the area where the surgical device will be navigated to so that the path will be displayed fully on the screen to better assist the operator when navigating the surgical device.

Regarding **claim 14**, Strommer '919 discloses the surgical device being a catheter (paragraph 0043). A guidewire would be an obvious alternative, often used in conjunction with a catheter as a means to guide the catheter (see 3/5/2000 definition of *guidewire* <http://cancerweb.ncl.ac.uk/omd/>).

10. **Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strommer '919 in view of Ueda '260, in further view of Maseda (U.S. 6,514,237).** Strommer '919 and Ueda '260 substantially disclose all the limitations as discussed above. Strommer '919 and Ueda '260 do not explicitly disclose a catheter portion made of an electroactive polymer. However, Maseda '237 discloses embedding electroactive polymer strands into catheters (C3, L58-60). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Strommer '919 and Ueda '260 to use a catheter with a portion made of an electroactive polymer as evidenced by Maseda '237. Such a modification would allow the catheter to be controlled with a high degree of precision (C2, L63-67).

11. **Claims 10, 11, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strommer '919 in view of Ueda '260, and further in view of Plicchi (U.S. 2004/0254566 A1).**

Regarding **claims 10 and 34**, Strommer '919 and Ueda '260 substantially disclose all the limitations as discussed above. Strommer '919 and Ueda '260 do

not explicitly disclose a moving mechanism with at least one moving element coupled to a plurality of angular movement rollers for twisting a catheter and another moving element coupled to a plurality of linear movement rollers to move said catheter along its longitudinal axis. However, Plicchi '566 discloses a moving mechanism for a catheter (Figure 3) with a moving element (Figure 3, Item 16) coupled to a plurality of angular movement rollers for twisting the catheter (Figure 3, Items 134 and 34) and another moving element (Figure 3, Item 17) coupled to a plurality of linear rollers for moving the catheter along its longitudinal axis (Figure 3, Items 125 and 25). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Strommer '919 and Ueda '260 to use the moving mechanism as evidenced by Plicchi '566. Such a modification would allow the catheter to be navigated in all directions while the operator is in a remote, shielded location (paragraph 0014).

Regarding **claim 11**, Strommer '919 substantially discloses all the limitations as discussed above. Strommer '919 does not explicitly disclose the use of a joystick to move the catheter. However, Ueda '260 discloses the use of a joystick (Figure 5, Item 50). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Strommer '919 in view of Ueda '260 to include the use of a joystick as evidenced by Ueda '260. Such a modification would allow the operator to control the moving mechanism while watching the image of the device being navigated (C10, L29-34).

12. **Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa '686 in view of Werp et al. (U.S. 6,015,414).** Gilboa '686 teaches the claims as discussed above but fail to explicitly teach at least one corrective movement when the orientation does not match the slope of the path at a certain location. However, in the same field of endeavor, Werp et al. teach at least one corrective movement when the orientation does not match the slope of the path at a certain location (Fig. 4). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Gilboa '686 to include the correction procedure in order to more accurately navigate the catheter to a destination (col. 4, lines 22-62).

13. **Claims 18-26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa '686 in view of Strommer '919.**

Regarding claims 18, 20-25, Gilboa '686 discloses the limitations as discussed above. Gilboa '686 does not disclose updating at least one of said topological representation according to an organ timing signal of an organ timing monitor coupled with a monitored organ of said body. However, Strommer '919 teaches the real-time reading of an organ timing signal for real-time visualization of the inspected organ which is then used to update the 3D image of the body (Para [0046]; also see claim 26). Strommer '919 also goes on to teach controlling the said moving mechanism according to the updated topological representation (Para [0047]). It would have been obvious to a person of ordinary skill in the art to modify Gilboa '686 to include the use of an organ

timing monitor in the application of updating topological images as evidenced by Strommer '919. Such a modification would allow for a moving organ to be displayed in real-time (Para [0021]).

Regarding **claim 19**, Strommer '919 teaches that the organ timing signal can be provided by an electrocardiogram monitor (Para [0053]).

Regarding **claim 26**, Strommer '919 discloses said display being used to display a superimposed topological representation on the display (paragraph 0047), which would require a 3D to 2D transformation in order for the 3D location to be matched to a 2D topological representation.

Regarding **claim 31**, Gilboa '686 discloses the limitations as discussed above but does not disclose the step of determining the shape of said distal portion. However, Strommer '919 teaches the possibility of extrapolating the shape of the surgical tool through a reconstructed 3D image (Para [0076]). It would have been obvious to a person of ordinary skill in the art to modify Gilboa '686 to include the step of determining the shape of the distal portion of the catheter as taught by Strommer '919. Such a modification would create a more detailed image of the catheter so that the operator can more precisely navigate it.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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8/11/2008